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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/814,972

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EXAMINER

CHAO, JUSTIN

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,972	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> Justin Chao	<b>Art Unit</b> 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 3, 4, 23, 24, 27, 30, 31, 32, 36 and 37 are objected to because of the following informalities: regarding claims 3, 4, 23, 37, and 24, 30 by their dependency, the claims fail to set forth structural limitations; regarding claim 27, the connector limitations appear to be redundant since the preamble is directed towards a guidewire and independent claim 1 already sets forth a guidewire proximal end sized and shaped for insertion into a connector; regarding claims 31 and 36, the recitation of "coaxial cable and/or connector" is indefinite; and regarding claim 32, the limitation "used to limit a respective guidewire to a single-use" appears to be a method step. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-22, 25-29, 31, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian 5,178,159 in view of Atalar et al 2002/0045816.

5. Regarding claims 1-12, 16-22, and 25 Christian teaches the invention as claimed: an inner conductor (98 fig 7; col 6, l. 55 - col 7, l. 28), an outer conductor coaxially disposed (99 fig 7; col 6, l. 55 - col 7, l. 28; col 6, ll. 52-54) about the inner conductor, a distal end sized and shaped for insertion into a subject (116 fig 8; col 7, ll. 38-48), a proximal end sized and shaped for insertion into a connector (figs 7 and 3; col 6, l. 55 - col 7, l. 28), an outer conductor contact (102 fig 7; col 6, l. 55 - col 7, l. 28), an extended section of the inner conductor (103 fig 7; col 6, l. 55 - col 7, l. 28), an electrically conductive material disposed at least partially around the inner conductor (103 fig 7; col 6, l. 55 - col 7, l. 28), an insulated area interposed between the outer conductive contact and the inner conductive contact (fig 7 and 29 ), an electrically insulating material disposed at least partially around the inner conductor (fig 7), the guidewire diameter is sized for insertion into the lumen of an anatomic structure of a subject (col 7, ll. 38-48), the anatomic structure is a blood vessel (col 7, ll. 38-48), the subject is a human (col 7, ll. 38-48), the guidewire diameter is less than about 0.040 inches (col 2, ll. 56-59), the diameter is between about 0.012 inches and 0.038 inches (col 2, ll. 56-59), the diameter is about 0.014 inches (col 2, ll. 56-59), a diameter of the inner conductor is between about 0.004 inches and about 0.012 inches (col 3, ll. 46-61),

the guidewire has a stiffness sufficient for insertion into a lumen of an anatomic structure of a subject (col 7, ll. 29-48), the guidewire is biocompatible (col 7, ll. 29-48), the guidewire comprises a conductive material (col 7, ll. 12-28), the guidewire is composed of nonmagnetic materials (col 3, ll. 22-28), the guidewire is sterilizable (col 3, ll. 22-26 further noting that any material may be sterilized), the outer conductor contact and the inner conductor contact are each annular in shape (102 and 103 fig 7; col 7, ll. 12-28), the outer conductor contact and the inner conductor contact have approximately equal diameters (102 and 103 fig 7; col 7, ll. 12-28), the inner conductor contact is disposed radially about a portion of the extended section of the inner conductor (102 and 103 fig 7; col 7, ll. 12-28), the insulated area is annular in shape (fig 7; col 7, ll. 12-28), the outer conductor contact is axially distal to the inner conductor contact (102 and 103 fig 7; col 7, ll. 12-28), an extension attachment coupled to the proximal end of the guidewire (col 1, ll. 24-49; col 5, ll. 18-68).

6. Regarding claims 26 and 33, Christian teaches where the inner conductor is a center conductor (fig 7; col 6, ll. 52-54 regarding connector portion of guidewire).

7. Regarding claims 27 and 34, Christian teaches a connector sized and configured to receive the proximal end of the guidewire. Further claimed limitation to attach to an MRI scanner and allow transmission of MRI signals amounts to a recitation of the intended use of the invention, without resulting in any structural difference between the claimed invention and the structure disclosed by Christian, and therefore fails to patentably distinguish the claimed invention from the prior art. See *In re Casey*, 152

USPQ 235 (CCPA 1967), MPEP 2115 [R-2] and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963), MPEP 2111.02.

8. Regarding claim 28, Christian teaches a connector capable of being releasably attachable to the conductors and therefore may be connected to any medical device with same connector system.

9. Regarding claim 1, Atalar et al teach within the field of MRI, the distal end of the guidewire defines an antenna configured to detect MRI signals (104 fig 1; para 73).

10. Regarding claims 1 and 25, with respect to the coaxial cable, and more specifically the inner and outer conductors, of the instant invention being configured to conduct the detected MRI signals to the proximal end of the guidewire, the applicant is advised that, while the features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 44 USPQ2d 1429. In addition, it has been held by the courts that apparatus claims cover what a device is, not what a device does. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 15 USPQ2d 1525 (Fed. Cir. 1990). In this case, the patented apparatus of Christian discloses (as detailed above) all the structural limitations of a guidewire required to perform the recited conduction of MRI signals.

11. Regarding claims 13-15, Atalar et al teach the guidewire comprises a superelastic material (para 96), the superelastic material comprises titanium (para 96), and the superelastic material comprises Nitinol (para 96).

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12. Regarding claims 29 and 35, Atalar et al teach electrical shielding (122 fig 1; paras 76-77 and 87-88) which would inherently inhibit RF interference.

13. Regarding claims 31 and 36, Atalar et al teach an MRI scanner interface circuit and connection detector (112 fig 1; paras 75, 92, 102 and 111)

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the guidewire system of Christian with the device of Atalar et al in order use the guidewire with MRI systems (para 9).

15. Claims 23, 24, 30, 32, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian 5,178,159 in view of Atalar et al as applied to claims 1 and 25 above, and further in view of Stern 5,743,903 et al.

16. Stern et al teach an identification parameter comprising at least one of a resistor value, a digital signature, or a unique serial number (col 13, l. 57 - col 14, l. 54), wherein the identification parameter is unique to a specific attachment. The invention of Stern et al would be capable of identifying that a proper combination of devices is used and to limit single use of an attachment.

17. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Christian in view of Stern et al in order to automatically recognize and apply custom settings to various attachments as taught by Stern et al (col 13, ll. 57-67).

### ***Response to Arguments***

18. Applicant's arguments with respect to claims 1-12, 16-22 and 25 have been considered but are moot in view of the new ground(s) of rejection.

19. It is further noted regarding Applicant's argument with respect to the conductors of Christian 5,178,159 "residing in a concentric space, but are not coaxially arranged," Examiner finds that since connectors are an integral part of a guidewire, the coaxial arrangement of the connectors of Christian, as noted by Applicant, reads upon the claimed "outer conductor coaxially disposed about the inner conductor" of the instant invention.

20. Regarding Applicant's argument that Christian "fails to teach or suggest an MRI compatible device, and does not even describe or mention MRI, much less a device that conducts RF/MRI signal," Applicant is advised that, while the features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 44 USPQ2d 1429. In addition, it has been held by the courts that apparatus claims cover what a device is, not what a device does. *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 15 USPQ2d 1525 (Fed. Cir. 1990). In this case, the patented apparatus of Christian discloses (as detailed above) all the structural limitations of a guidewire required to perform the recited conduction of MRI signals.

21. Regarding Applicant's arguments with respect to claims 13-15 that Atalar et al "does not describe a guidewire, but a sleeve..." Examiner finds that Atalar et al disclose a guidewire comprising a coaxial cable (fig 7; para 102).

22. Regarding Applicant's arguments with respect to claims 23 and 24 that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to



produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Further in response to applicant's argument that Stern is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the Applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Stern et al addresses the particular problem of identifying attached components in a medical system via unique identification parameters. Stern et al's teaching of an identification signal which uniquely identifies the particular physical and/or performance characteristics of the connect component (col 13, ll. 57-62) is reasonably pertinent to the instant invention and reads upon the claimed identification parameter.

### ***Conclusion***

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Justin Chao whose telephone number is (571)270-3072. The examiner can normally be reached on Mon-Fri, alt Fri off, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justin Chao/  
8/13/07

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737